TSCA NON-CONFIDENTIAL BUSINESS INFORMATION		
DOCUMENT DESCRIPTION	**DOCUMENT CONTROL Nº**	**DATE RECEIVED**
PC4155		

COMMENTS:

MC= 301 Research and Development

DOES NOT CONTAIN CBI

PC 4155

MUTEK
MUETEK ANALYTIC, INC.

April 30, 2001

Dear Mr. Schutz,

With this letter and attachments I would like to present the history of a chemical used in our German mother company since 1989. The American office imported it and used it from 1994 through 1998 until I received a phone call from one of our customers wanting to know if this chemical is on the TSCA list. We did not know and therefore stopped selling this product and got started to collect information.

The consulting company Dames and Moore handled our case. We soon knew that the chemical was not on the non-confidential part of the TSCA list. However this chemical had been used as an ingredient of a sports ointment produced by a pharmaceutical company (Hoechst, Frankfurt), therefore it raised our hopes to be on the confidential inventory.

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Together with our lawyer and Ms. Erin Tesch from Dames and Moore an inquiry was prepared and sent to the EPA in September 1999. We never received a written notice from the EPA but I had two telephone conversations with Mr. Tim Thomas. He verbally informed me that the product is not on the confidential part of the TSCA inventory. Therefore our company had to file a Premanufacture Notice (PMN) for new chemical substances.

Having spent already quite a bit of money compared with little business we make with this product and the fact that there was an alternative product on the American market, I decided against proceeding with a PMN.

Recently we had chemists visiting our company. One of their complaints referred the alternative product that we have been offering since then. Letting them know why our company made this decision the majority of them found our behavior totally needless because we fall under the Research and Development Exemption.

I am aware that an importer need not apply for the R&D exemption but giving our history I am asking for your professional opinion in our case.

Would you be so kind and have a look at the following pages (even after this very long introduction) and let me know what you think? Your support would help me a lot.

Thanks in advance.

Best regards,

Elke Pross

Elke Pross
Muetek Analytic, Inc.
Phone: 770 612 0606
Fax: 770 955 2383
Email: elke.pross@muetek.com

• Description of Application

Muetek Analytic manufactures analytical instruments mainly for the paper industry. One instrument, the Particle Charge Detector, is used as an endpoint detector for colloidal titrations. Customers receive a cationic and an anionic polyelectrolyte standard solution.
PES-Na (Sodium Poly Ethylene Sulfonate) is an excellent anionic standard and is used in a diluted form (0.130 g/liter).

• Use of Substance – R&D Exemption

Muetek Analytic, Inc. believes to fall under a self-executing PMN. It does not require EPA's approval because Muetek used and intends to use the chemical for Research and Development purposes only. The product is applied to

- Test or demonstrate Muetek Analytic's equipment (Particle Charge Detector)
- As a quality control chemical to test performance characteristics

- Muetek Analytic, Inc. conducts R&D activity in their application laboratory using prudent laboratory practices.

- As importer Muetek Analytic, Inc. supervises the use of PES-Na with a technically qualified individual. Muetek Analytic, Inc. employs a person who by education, training and experience can evaluate any potential risks associated with PES-Na. The person can appreciate the risks from exposure to PES-Na and can minimize those risks.

- Muetek Analytic, Inc. keeps records documenting compliance with prudent lab practices. Documented is the name of employee preparing the solution, date of preparation, amount of chemical used and results of each control titration.

- Muetek Analytic, Inc. maintains records of all customers that have been provided with PES-Na including the amount of the distributed chemical.

- Muetek customers using PES-Na are provided with a MSDS (MSDS attached).

- Muetek Analytic, Inc. sold or distributed small quantities in the past as listed in the table below. Future distributions will be similar to 1997/1998.

Product	Year	Quantity sold in grams pure substance
PES-Na Sodium Poly Ethylene Sulfonate	1994	14
	1995	16
	1996	20
	1997	20
	1998	119

Elke Pross
April 30, 2001
Elke Pross
Muetek Analytic, Inc.

Material Safety Data Sheet

Section 1 - Identification

Product:	PES-Na
Chemical family:	Organic anionic polyelectrolyte
Chemical Name:	Sodium Poly Ethylene Sulfonate
Other names:	Sodium Apolate, Sodium Poly Vinyl Sulfonate
Formula:	$(C_2H_4SO_3)_x \cdot xNa$
CAS-Number:	25053-27-4
Description:	Crystalline powder, odorless

Section 2 - Hazardous Ingredients

Irritant
Irritating to eyes, respiratory system and skin

Section 3 - Physical Properties

Appearance and odor:	white, yellowish, odorless
Boiling point (°C):	not applicable
Melting point (°C):	not determined
pH (100 g/H_20)	5 - 7
Solubility in water (20 °C)	850 g/l
Solubility in other solvents	not determined

Section 4 - Fire and Explosion Hazard Data

Extinguishing media:	Use media appropriate for type of fire and combustibles in area, e.g. water, extinguishing foam, powder, carbon dioxide, sand.
Special fire fighting procedures:	Firefighters should wear normal protective- and respiratory equipment. Respiratory equipments should be independent from circulating air.
Unusual fire and explosion hazards:	Emits toxic fumes under fire conditions

Section 5 - Reactive Data

Stability :	stable
Incompatibility:	Do not store with strong oxidizing agents Store in a dry place
Hazardous combustion or Decomposition products:	Toxic fumes of Carbon Monoxide, Carbon Dioxide, Sulfur Oxides

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Ms Elke Pross
Muetek Analytic, In.
Suite 114, 2141 Kingston Court, SE
Marietta Georgia 30067

MAY 13 2002

CONTAINS NO CBI

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Re: PC-4155

Dear Ms Pross:

This letter responds to your letter dated 30 April 2001, and sent to Dave Schutz of my staff, in which you asked that the Agency provide a written opinion on whether your company's use and sale of sodium poly ethylene sulfonate ('PES-Na') can be permitted under the research and development ('R&D') exemption from the requirement under the Toxic Substances Control Act ('TSCA') that premanufacture notification ('PMN') be filed for commercial use of a new chemical substance not included in the TSCA Inventory of chemical substances. Regrettably, your inquiry was assigned to an employee who left our office soon after it was received, and we were not aware that you had not received an answer. I am sorry for the inconvenience this has caused you.

In your letter, you describe your situation as follows: from 1994 to1998, your company manufactured (imported) PES-Na, for use as a reagent in determining whether titrations have gone to completion. In 1998 one of your customers asked you whether the PES-Na was on the TSCA Inventory, and you determined that it was not. You decided that the commercial value of the material did not justify the cost of filing a PMN and withdrew the material from sale in the US. You offered a substitute material to your customers. Since that time, your customers have told you that PES-Na works better than the substitute, and that they are puzzled by your action in withdrawing the material because it can qualify for the R&D Exemption. Your letter asked that the Agency concur with your understanding that the material can meet the conditions for exemption from premanufacture notification ("PMN") under §5 of the TSCA described at 40 Code of Federal Regulations ("CFR") §§720.36 and 78 ('the R&D exemption').

Chemical substances used exclusively for R&D are eligible for the R&D exemption under 40CFR §§720.36 and 78 if their manufacturers meet all the requirements associated with the exemption. The substance must either be the focus of R&D itself, or be used in an R&D activity focusing on another chemical substance. The latter category encompasses reagents, chemicals to be used as standards for chemical analysis in laboratories, and intermediates used solely to produce R&D substances, including intermediates used in the production of pesticides used exclusively for R&D. Based on your discussion of the use of your material, it is being used as a reagent, so can qualify for the R&D exemption. As you noted in your letter, you need not apply to the Agency for permission to use the R&D exemption. However, it is your responsibility to determine that your use is consistent with the exemption and to keep adequate records of your determination and your use which conform to the requirements at 40CFR §720.78. The required records are summarized in the table below. Manufacturers must keep records documenting compliance with the requirements imposed by the exemption for 5 years.

Ms Elke Pross
Muetec Analytic, Inc
Suite 114, 2141 Kingston Court, SE
Marietta Georgia 30067

Re: PC-4155

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CONCURRENCE		
SYMBOL	7405	7405
SURNAME	Schutz	Gerber w/comments
DATE	January 2, 2002	1/3/02

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